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| 10/584,242      | 06/23/2006  | Yusuke Murakawa      | 084437-0169         | 1685             |

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

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| EXAMINER |
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DICKINSON, PAUL W

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| ART UNIT | PAPER NUMBER |
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1618

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02/16/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/584,242 | <b>Applicant(s)</b><br>MURAKAWA ET AL. |  |
|                              | <b>Examiner</b><br>PAUL DICKINSON    | <b>Art Unit</b><br>1618                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5,6,22-33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 6 and 22-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group I in the reply filed on 12/1/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6 and 22-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following limitation in claim 5 is not supported by the application:

Art Unit: 1618

“said product is prepared by any one of (i) to (iv) below:

(i) a production method comprising mixing at least the compound with poor wettability and the surfactant, adding thereto water or an aqueous solution of a binder, kneading the mixture, and compressing the kneaded product to give granules;

(ii) a production method comprising mixing at least the compound with poor wettability and the surfactant to give a mixed powder, and spraying thereon water or an aqueous solution of a binder while agitating, tumbling or fluidizing the mixed powder to coat the mixed powder and give granules;

(iii) a production method comprising preparing a composition containing at least the compound with poor wettability, kneading the composition while adding thereto water or an aqueous solution of the surfactant and a binder, and compressing the kneaded product to give granules; or

(iv) a production method comprising preparing a composition containing at least the compound with poor wettability, and spraying thereon water or an aqueous solution of the surfactant and a binder while agitating, tumbling or fluidizing the composition to coat the composition and give granules.

“

This limitation is not explicitly stated by the specification or original claims.

Further the specification and original claims do not support this limitation implicitly through a representative number of examples. The portion of the specification that is closest to the limitation above is at paragraphs 60-61:

[0060] The granulated product can be prepared by a common method (for example, 10<sup>th</sup> Edition, General Provision of Preparation, Japanese Pharmacopoeia). Specifically, (granulated) powdered drugs, fine granules, or granules can be produced by adding an excipient (for example, lactose, saccharose, glucose, starch, sucrose, crystalline cellulose, licorice powder, mannitol, sodium hydrogen carbonate, calcium phosphate, calcium sulfate, and the like), a disintegrant (for example, starch, calcium carbonate, and the like), and the like, if necessary, in addition to the low water-soluble compounds and the surfactant are added and mixed, a binder solution dissolved in an aqueous solvent (for example, water, water/ethanol, water/isopropanol, water/acetone, and the like) is added thereto, and the mixture is kneaded and compressed for granulation, or by putting a mixed powder containing low water-soluble compounds, a surfactant, and other additives into a granulator (for example, a tumbling granulator, a fluidized bed granulator, and the like) and spraying a binder solution dissolved in an aqueous solvent thereon to coat the mixed powder. The concentration of the binder in the binder solution may be about 3 to about 15% by weight. Further, the amount of the binder to be used may be one such that the weight ratio of the binder to the low water-soluble compound is about 2 to about 5%.

[0061] Alternatively, in each of the above-described methods, instead of mixing the low water-soluble compounds and the surfactant before the granulation, a surfactant may be blended by incorporating the surfactant into the binder liquid during the granulation. Particularly, a method wherein fluidized bed granulation is carried out with a binder solution incorporated with a surfactant is preferably carried out. In the case where the binder solution contains a surfactant, the concentration of the surfactant in the solution is not particularly limited as long as the weight ratio of the surfactant to the low water-soluble compound is about 0.001 to about 2 in the obtained granulated product, but it is preferably about 1 to about 1,000 mmol/L, and more preferably about 10 to about 100 mmol/L.

The above section does not support the limitation of claim 5. The methods disclosed in the section above (paragraphs 60-61), and the methods disclosed in claim 5, are not the same.

Regarding preparation (i) in claim 5, the above section discloses a production method comprising adding an excipient and an optional disintegrant to a low water-soluble compound and surfactant, mixing, adding thereto a binder solution dissolved in an aqueous solvent, kneading, and compressing for granulation. By contrast, preparation (i) in claim 5 does not require an excipient. Further, preparation (i) states

Art Unit: 1618

that the kneaded product is compressed to give granules. "Compressing for granulation" is not the same as "compressed to give granules", rather "compressing for granulation" means preparing the product for granulation. Nowhere in the section above or elsewhere does the specification support "compressed to give granules".

Regarding preparation (ii) in claim 5, the above section discloses a production method comprising putting a mixed powder containing low water-soluble compounds, a surfactant, and other additives into a granulator and spraying a binder solution dissolved in an aqueous solvent thereon to coat the mixed powder. By contrast, preparation (ii) in claim 5 does not require adding additives. Further preparation (ii), does not require a granulator, as the above section does. Further, the section above does not teach "spraying thereon water or an aqueous solution of a binder while agitating, tumbling, or fluidizing the mixed powder".

Regarding preparation (iii) in claim 5, the above section discloses a production method comprising adding an excipient and an optional disintegrant to a low water-soluble compound and surfactant, mixing, adding thereto a binder solution dissolved in an aqueous solvent, kneading, and compressing for granulation. The above section further states that the surfactant may instead be blended by incorporating the surfactant into the binder liquid during granulation. By contrast, preparation (iii) in claim 5 does not require an excipient. Further, preparation (iii) states that the kneaded product is compressed to give granules. "Compressing for granulation" is not the same as "compressed to give granules", rather "compressing for granulation" means preparing

Art Unit: 1618

the product for granulation. Nowhere in the section above or elsewhere does the specification support "compressed to give granules".

Regarding (iv) in claim 5, there is no disclosure in the section above or elsewhere in the specification, of "a production method comprising preparing a composition containing at least the compound with poor wettability, and spraying thereon water or an aqueous solution of the surfactant and a binder while agitating, tumbling or fluidizing the composition to coat the composition and give granules". There is no statement in the section above or elsewhere in the specification that Applicant had envisioned this limitation at the time of filing, nor is there a representative number of examples of this production method that show Applicant had envisioned this limitation at the time of filing.

For these reasons, because the method steps of claim 5 are not explicitly or implicitly disclosed in the original application, the skilled artisan would not accept that Applicant had possession of the invention at the time of filing.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 22-27, and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "the weight ratio of the surfactant to the compound is about 0.001 to less than 0.1" in claim 5 is unclear. Specifically, it is unclear if "about" qualifies only

Art Unit: 1618

"0.001" or if "about" qualifies the range as a whole (i.e. "(about 0.001) to less than 0.1" or "about (0.001 to less than 0.1)").

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



Claims 5, 6 and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20040076675 ('675). '675 discloses a granulated product (abstract), wherein the product comprises a slightly water-soluble component (a compound with poor wettability) and a surfactant (paragraphs 10-11), the weight ratio of the surfactant to the compound may be 0.01 to 0.1 (paragraph 59), the particle size is less than 420 microns (Example 1) or less than 500 microns (Examples 2-27), wherein the product is prepared by a production method comprising mixing at least the compound with poor wettability and the surfactant, adding thereto water or an aqueous solution of a binder, kneading the mixture (paragraph 31; examples), and compressing the kneaded product into granules (paragraph 68). The teaching of '675 of a weight ratio of the surfactant to compound of 0.01 anticipates Applicant's range of "about 0.001 to less than 0.1" (instant claim 5) and about 0.005 to about 0.05" (instant claim 6). A hydrophilic polymer is also present in the granulated product, which is preferably hydroxypropyl cellulose or hydroxypropyl methyl cellulose (binders) (paragraph 57; examples). In Example 1, hydroxypropyl cellulose is present in 2 wt% (calculated from  $0.02/(0.05 + 0.1 + 0.6 + 0.25 + 0.02)$ ). 2 wt% anticipates Applicant's range of "about 2 to about 5%" (instant claim 26). Excipients may be added and may be present from 0 to 1000 fold the weight of the slightly water-soluble component (paragraph 65) (claim 26), although Applicant's range of about 20 to about 60% by weight is not disclosed. '675 teaches making tablets from the granulated product (forming a molded product by molding the granulated product) (paragraph 68) (instant claims 27-26).

'675 fails to teach "at least 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve" (instant claim 5). '675 further fails to teach "about 20 to about 60% by weight" for its excipients. '675 further fails to teach the angle of repose disclosed in instant claims 22-24.

It would have been obvious to one of ordinary skill in the art to find the particle size of the granulated product which corresponds to "at least 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve". A 100-mesh sieve has a sieve diameter of 152 microns. Accordingly, the limitation "at least 35% by weight with respect to the total weight of the product does not pass through a 100-mesh sieve" is the equivalent of saying "at least 35% by weight with respect to the total weight of the product has a particle size of 152 microns or more". '675 teaches particle sizes of "420 microns or less" and "500 microns or less". The particle size ranges taught by '675 ("420 microns or less" and "500 microns or less") overlap with the Applicant's particle size range ("152 microns or more"). It would have been obvious to find Applicant's particle size of "152 microns or more", through routine experimentation, as this range overlaps with the ranges taught by '675 of "420 microns or less" and "500 microns or less". Similarly, it would have been obvious to find Applicant's range of "about 20 to about 60% by weight" of excipients (components in the granulated product other than the compound with poor wettability and surfactant), through routine experimentation. '675 provides sufficient guidance to this end, as it teaches the excipient may be present in 0- to 1000- fold the amount of slightly water-soluble component. In Example 1, the amount of components other than the slightly

Art Unit: 1618

water soluble component and surfactant is 85 wt% (calculated from  $85 = (0.6 + 0.25 + 0.02)/(0.05 + 0.1 + 0.6 + 0.25 + 0.02)$ ). However, '675 teaches the amount of excipients present may be as low as 0-fold the amount of slightly water-soluble component. Thus, '675 contemplates values less than 85%, i.e. values between 0% excipient to 85% excipient. Thus, it would be obvious to find Applicant's range of "about 20 to about 60% by weight" as this is fully encompassed by the range suggested by '675 of 0 to 85 wt%.

Regarding the angle of repose disclosed in instant claim 22-24, although '675 does not appreciate that its granulated product has the presently claimed angle of repose values, it must inherently have these angle of repose values. A composition cannot be separated from its properties. The granulated product of '675 is structurally identical to the claimed granulated product. Based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties disclosed in instant claims 22-24 would inherently be present in the granulated product of '675. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

### ***Conclusion***

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAUL DICKINSON/  
Examiner, Art Unit 1618

February 10, 2011